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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,721	08/17/2001	Yoshio Hiraki	2114631US0PC	2653

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[REDACTED] EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/913,721	HIRAKI ET AL.
Examiner	Art Unit	
Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 April 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Receipt is acknowledged of Amendment filed on April 10, 2003. The finality of the previous Office action dated February 12, 2003 is withdrawn in view of the applicants' remarks made during the telephone interview on March 12, 2003.

Rejections under 35 U.S.C. § 103 over Maybeck in view of Yakult abstract, and over Maybeck and Yakult abstract and further in view of Yiournas et al. are withdrawn in view of applicants remarks. The obviousness rejections over Mathur and over Mathur in view of Yiournas et al. are maintained with few changes to meet the amended limitation. Claims 1-13 are pending.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "comprising a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s) as a main component" renders the claim vague and indefinite, as it is not clear whether the "main component" is only essential component in lamellar structure; whether the presence of other lipids such as cholesterol in or out of the lamellar structure would meet the limitation. The claim is confusing because it is not clear what is open-ended and close-ended. Examiner also notes that, while applicants name fatty acid

monoglycerides as "a main component", the claim is in fact open to the presence of other components such as cholesterol, which, according to prior art, is necessary to form lamellar structure, and are also used in all of the example formulations in applicants' specification. See spec., Table 5, containing cholesterol, and Table 6, containing cholesterol and monoalkyl glyceryl ethers. Instant claim 11 also requires cholesterol. The declaration filed on October 29, 2002 also indicates that the sample used in the comparison with Maybeck contains cholesterol.

The remaining claims are rejected as depending on indefinite claims.

Examiner also notes that the term "derivatives thereof" in instant claims renders the claims vague and indefinite. Applicants' specification indicates that any of "retinol, retinal of the aldehyde type, retinoic acid of the carboxylic acid type. . . vitamin A precursors such as beta-carotin and decomposed products of vitamin A" are referred as "vitamin A". See spec. 6, lines 1 – 15. It is not clear, from the applicants' disclosure, the metes and bounds of the scope of the term "derivatives".

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur (US 5260065).

Mathur teaches paucilamellar lipid vesicles made of a blend of amphiphilic lipids. The reference teaches that glyceryl monostearate is among the most

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preferred lipids used. See col. 3, lines 41 – 51. See instant claims 12 and 13.

While the reference teaches that the lipids therein are not capable of forming lamellar by itself, secondary lipids and/or cholesterol is used to form lamellar phase. See col. 3, line 65 – col. 4, line 11.

Examples 2 and 5 illustrate retinoic acid formulations wherein the retinoic acid is encapsulated within the vesicles. Example 5 employs glyceryl distearate and cholesterol. While Mathur does not show specific formulation comprising glyceryl monostearate, the reference teaches that glyceryl monostearate is nevertheless a preferred lipid in the invention.

Regarding the transitional phrase, "consisting essentially of", it is well settled in patent law that absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See MPEP § 2111.03. PPG Industries v. Guardian Industries, 156 F.3d 1351, 1355, 48 U.S.P.Q. 2d 1351, 1355 (Fed. Cir. 1998). In this case, the specification indicates that the present invention also contains cholesterol. It is viewed that applicants bears the burden of showing the presence of oil materials other than fatty acid monoglycerides materially affect the basic and novelty of the invention. Examiner construes the term "consisting essentially of" as "comprising" in this case as there is no clear indication in specification, claims, and declaration that the presence of lipids such as cholesterol materially affects the basic and novel characteristics of the claimed invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the exemplified formulations in Mathur by substituting the glyceryl distearate with glyceryl monostearate as motivated by the reference, because of the expectation of successfully producing a lamellar vesicle composition with similar properties.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur claims 1-8 and 9-13 above, and further in view of Yiournas et al. (US 5013497).

While Mathur is directed to paucilamellar vesicles, the reference does not teach multilamellar structures.

Yiournas generally teaches the advantages of both types of vesicles. According to the reference, while paucilamellar vesicles can transport large quantities of aqueous or lipophilic materials, their large size can preclude approach to certain tissues. See col. 1, lines 42 –68. Multilamellar vesicles are on the other hand said to be "best for encapsulation or transportation of lipophilic materials" because of the relatively large amount of lipid in the lipid bilayers therein. See col. 1, lines 53 – 60. No disadvantage associated with the size of the multilamellar vesicle structure is mentioned.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the paucilamellar vesicle formulations in Mathur by formulating multilamellar vesicles as motivated by Yiournas because of the expectation of successfully producing lipid vesicles that can similarly encapsulate and transport large quantities of lipophilic materials.

***Responses to Arguments***

Applicant's arguments with respect to claims 1-13 have been considered but are not moot in view of the new grounds of the rejection in part and not persuasive in part. See the rejection over Mathur above.

Examiner also notes that unexpected results must be shown by clear and convincing evidence that is commensurate with the scope of the claim. See MPEP § 716. 02. In this case, in claims 1-3, 5, 10, 12, and 13, no limitation is recited as to the weight amount of fatty acid monoglyceride and vitamin A and derivatives thereof, while the example in Table 5 used 6.0 % by weight of glyceryl monopalmitate and 0.3 % by weight of retinol palmitate. This is 20 parts by weight of the fatty acid monoglycerides per part by weight of vitamin A. Table 6 also shows 5:1, 10:1, 4:1, 100:1 weight ratio of glyceryl monopalmitate and vitamin A. The data of alleged unexpected result is not commensurate with the scope of the claims 1-3, 5, 10, 12, and 13.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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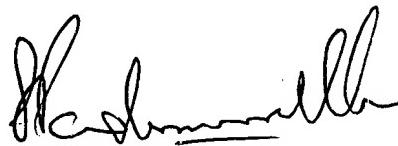
action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
May 1, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
